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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,797	04/21/2004	Herbert M. Dean	dean0404con	5067

23580 7590 03/23/2007
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EXAMINER	
JAGOE, DONNA A	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,797	DEAN ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 30, 2006 has been entered.

Claims 1-14 are pending in this application.

Applicants' arguments filed August 30, 2006 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Pepine, American Journal of Cardiology No. 77 June 20, 1996.

Pepine teaches the importance of treating CAD (coronary artery disease) patients with aspirin and beta-blockers (see table V, page 4D), teaching that the goal is to prevent death, nonfatal MI and hospitalization, while improving quality of life. Pepine further teaches that aspirin and beta-blockers are an important part of attempting to influence prognosis in CAD patients, especially after myocardial infarction (MI) (page 5D last paragraph of column 1 bridging to column 2).

Claims 1-7 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powell et al. U.S. Patent No. 6,140,319 A. and Pepine, American Journal of Cardiology No. 77 June 20, 1996.

Claims 1-7 and 14 are drawn to a medicament dosage unit consisting essentially of a beta-adrenergic blocker and a platelet inhibitor in a single unit. Dependent claims are drawn to aspirin as the platelet inhibitor and atenolol, propranolol, timolol and metoprolol as the beta-blockers.

Claims 12 and 13 are drawn to a method of making a cardiovascular protective dosage unit comprising a single dosage unit consisting essentially of a beta-adrenergic blocker and a platelet inhibitor

Powell et al. teach a single dosage unit of a vasopeptidase inhibitor combined with a beta-blocker and an antiplatelet agent (column 2, lines 5-13). It differs in that it includes a vasopeptidase inhibitor. The transitional phrase "consisting essentially of"

limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52. For the purposes of searching for and applying prior art under35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." If the applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USP 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989). It does not appear that the addition of a vasopeptidase inhibitor would materially change the characteristics of the applicant's invention, since a vasopeptidase inhibitor would also treat cardiovascular disease.

Since applicant provides no details regarding the method of making a medicament, it reads on the "single dosage form" of the prior art. Powell et al. teach the compositions useful for cardiovascular disorders such as angina pectoris (column 1, line 66 to column 2, line 1). Beta-blockers for the invention include agents such as propranolol, timolol, metoprolol and atenolol and antiplatelet agents such as aspirin (column 4, lines 6-28).

Pepine teaches the importance of treating CAD (coronary artery disease) patients with aspirin and beta-blockers (see table V, page 4D), teaching that the goal is

to prevent death, nonfatal MI and hospitalization, while improving quality of life. Pepine further teaches that aspirin and beta-blockers are an important part of attempting to influence prognosis in CAD patients, especially after myocardial infarction (MI) (page 5D last paragraph of column 1 bridging to column 2).

Response to Arguments

Applicant asserts that there is an increased cardiac morbidity and mortality in patients with coronary artery disease resulting from the interaction of aspirin combined with an ACE inhibitor. In response, the Pepine reference teaches that a prognosis is influences principally by 2 variables, severity of ischemia and severity of left ventricular dysfunction, however there are other factors that interact with these factors such as age, gender, genetic background as well as blood pressure, lifestyle, serum lipids, endocrine-metabolic status and behavior (page 3D, column 2). The method of improving prognosis is detailed in page 4D at tables I through V. Of further note is that applicant is claiming all beta-blockers in claims 1-3 and 8-14. The reference teaches that the clinician must be cautious when considering drugs used in patients with cardiac ischemia because all drugs within a certain pharmacologic class may not have the same clinical response and this could limit the anticipated improvement in prognosis, e.g., the beta-blocker class includes agents with ancillary properties (e.g. sympathomimetic or vasodilatory activity). In general, beta-blockers with these ancillary properties (e.g. oxprenolol, alprenolol and pindolol) have not been shown to improve

survival to the same extent as beta-blockers without such ancillary properties (page 4D column 2 paragraph 2).

Applicant asserts that there is increased restenosis after stenting resulting from interaction of aspirin combined with an ACE inhibitor. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that there is increased restenosis after stenting when employing an ACE inhibitor and aspirin) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims are directed to a method of treatment and a medicament for treatment of cardiovascular disease, not for restenosis or prognosis after stenting.

Applicant asserts that there is increased mortality in patients with coronary artery disease resulting from interaction with beta blockers combined with an ACE inhibitor and an angiotensin-receptor blocker.

In response, the Pepine reference teaches that a prognosis is influenced principally by two variables, severity of ischemia and severity of left ventricular dysfunction, however there are other factors that interact with these factors such as age, gender, genetic background as well as blood pressure, lifestyle, serum lipids, endocrine-metabolic status and behavior (page 3D, column 2). The method of improving prognosis is detailed in page 4D at tables I through V. Of further note is that applicant is claiming all beta-blockers in claims 1-3 and 8-14. The reference teaches

that the clinician must be cautious when considering drugs used in patients with cardiac ischemia because all drugs within a certain pharmacologic class may **not** have the same clinical response and this could limit the anticipated improvement in prognosis, e.g., the beta-blocker class includes agents with ancillary properties (e.g. sympathomimetic or vasodilatory activity). In general, beta-blockers with these ancillary properties (e.g. oxprenolol, alprenolol and pindolol) have not been shown to improve survival to the same extent as beta-blockers without such ancillary properties (page 4D column 2 paragraph 2).

Regarding applicants allegation regarding fetal malformations associated with ACE inhibitors, applicant appears to confuse the requirements for patentability with those of receiving FDA approval. See e.g. In re Anthony, 414 F.2d 1383, 1395, 162 USPQ 594, 604 (CCPA 1969). Accordingly, the argument concerning fetal malformations is not convincing.

Regarding applicants argument over anaphylactoid reactions, again, applicant appears to confuse the requirements for patentability with those of receiving FDA approval, see above. However, anaphylactic reactions occur with events such as bee stings. Triggers of anaphylaxis include all types of substances. Only a trace amount of the trigger may be needed to cause a severe reaction. Even the substances instantly claimed are possible causative agents to an anaphylactic reaction.

Response to Exhibits

Applicants rely on several post-filing date references that allegedly provide evidence that their claimed invention is patentable. The examiner has considered these references, however, since they were not available to those skilled in the art at the time this application was filed, they are not convincing. The determination of obviousness or nonobviousness must be based upon what was known in the art at the time the invention was made. See 35 U.S.C. § 103: "A patent may not be obtained.., if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art" (emphasis added).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe
Patent Examiner
Art Unit 1614

March 7, 2007

Ardin H. Marschel 3/18/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER